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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/085,072	03/01/2002	Bozidar Ferek-Petric	P-8158.02 DIV1	1422
27581	7590	01/25/2006	EXAMINER	
MEDTRONIC, INC. 710 MEDTRONIC PARK MINNEAPOLIS, MN 55432-9924			OROPEZA, FRANCES P	
			ART UNIT	PAPER NUMBER
			3766	

DATE MAILED: 01/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

### Period for Reply

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 11/9/05 (Amendment).  
 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 35,37-39 and 48-51 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 35,37-39 and 48-51 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

*Response*

1. In the response of 11/9/05, the Applicant amended at least the independent claims hence the rejection of record is withdrawn and a new rejection established in the subsequent paragraphs.

*Claim Rejections - 35 USC § 112*

2. Claims 37, 38, 49 and 50 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

As to claims 37 and 49, the Examiner is unable to find a “non-generically active” therapeutic drug in the original specification.

As to claims 38 and 50, the Examiner is unable to find a programmer means for “remotely” programming the signal processing means in the original specification.

New matter may not be added at this point in the prosecution. Appropriate correction is required.

3. Claims 35-39 and 48-51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 35, line 14, and in claim 48, line 14, “respectively” is vague. Appropriate correction is required.

***Claim Rejections - 35 USC § 103***

4. Claims 35, 37-39 and 48-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soykan et al. (US 6206914) in view of Thompson et al. (US 5800465).

Soykan et al. teach an implantable system with drug treatment that monitors ECG (electrical) signals and coronary sinus blood flow signals to detect and treat ischemia (fig. 5; col. 1 @ 23-39; col. 2 @ 30-40; col. 3 @ 23-30; col. 4 @ 18-23; col. 5 @ 21-36; col. 13 @ 46-64; col. 16 @ 23-46). Soykan et al. teach modifying and incorporating the stimulation device of US 5702427 to Ecker et al. (col. 16 @ 53-58), hence including atrial and ventricular sensing means and signals in the instant invention (fig. 9). The sensing elements monitor changes in the circulatory system, inherently occurring over a period of time, where a reduction of blood flow, read to be about a 25% decrease in blood flow, can be indicated by changes in the ST segment (col. 5 @ 21-28). The acoustic doppler sensor is recognized to be a doppler flow meter (col. 16 @ 49).

As to claim 37, the drug dispensing means dispenses a therapeutic agent, read to be a non-generic active therapeutic drug (abstract).

As to claim 38, the telemetry system used in the instant invention, a Medtronic Model 9790 programmer (specification – page 5, line 25), is the same programmer used in the Soykan et al. reference (col. 15 @ 18), hence Soyken et al. teach “remotely programming the signal processing means via a wireless telemetry link”.

As discussed in the previous three paragraphs of this action, Soykan et al. disclose the claimed invention except for coronary vein sense means disposed within a portion of a coronary sinus or great vein comprising at least one electrode and a flow meter (claims 35 and 43).

Thompson et al. teaches cardiac monitoring using coronary vein sense means disposed within a portion of a coronary sinus or great vein comprising at least one electrode (fig. 1c - 31, 32, 33) and a flow meter (doppler flow meter substituted for the electrodes 141, 142 in fig 1c – col. 14 @ 7-12) for the purpose of accurately sensing the cardiac signal (figures 1(c), 4A; col. 8 @ 27-29; col. 9 @ 38-40; col. 11 @ 52-59; col. 13 @ 5-8; col. 14 @ 1-12). It would have been obvious to one having ordinary skill in the art at the time of the invention to have had the coronary vein sense means disposed within a portion of a coronary sinus or great vein comprise at least one electrode and a flow meter in the Soykan et al. system in order to place the electrode and flow meter on the same lead to reduce the amount hardware that must be implanted to achieve atrial and ventricular sensing, and to make the sensing and treatment site specific, hence providing optimal care by monitoring the cardiac signal near the impacted area, controlling and delivering the drug to the locally impacted area based on the locally sensed signals, and treating the patient rapidly at the locally impacted area to prevent significant physiological damage from occurring (Thompson et al. – col. 5 @ 20-23; col. 6 @ 25-29) and (Soykan et al. – col. 1 @ 51-55; col. 2 @ 54 – col. 3 @ 5; col. 3 @ 22-30; col. 15 @ 25-28; col. 16 @ 10-11 and 42-61).

*Specification*

5. The amendment filed 9/9/05 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: in claims 37 and 49, the limitation in quotations: a “non-generically active” therapeutic drug and in claims 38 and 50, the limitation in quotations: a programmer means for “remotely” programming the signal processing means.

Applicant is required to cancel the new matter in the reply to this Office Action.

*Objections*

6. On page 6, line 25 of the specification, it appears the patent number should be --4556063--.

7. The patent number on page 5, line 29 of the specification is not a Wyborny et al. patent.

*Statutory Basis*

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

*Conclusion*

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


Art Unit: 3766

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fran Oropeza whose telephone number is (571) 272-4953. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272-6996. The fax phone numbers for the organization where this application or proceeding is assigned is (571) 273-8300 for regular communication and for After Final communications.

Frances P. Oropeza  
Patent Examiner  
Art Unit 3762

*FPO*  
*1/29/06*

  
Robert E. Pezzuto  
Supervisory Patent Examiner  
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